IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MORTON GROVE PHARMACEUTICALS, INC. Plaintiff, v. THE NATIONAL PEDICULOSIS ASSOCIATION, INC., Defendant.	)	No: 08-CV-1384 Judge Bucklo Magistrate Judge Mason

MORTON GROVE'S REPLY IN SUPPORT OF ITS MOTION TO STRIKE ALLEGATIONS AND DEFENSES IN DEFENDANT'S ANSWER AND COUNTERCLAIM

Morton Grove's motion to strike addresses two separate and distinct issues—(1) the NPA's defenses and (2) the NPA's inclusion of irrelevant and improper references to the boxed warning for lindane medications, and to an initial agency warning letter sent by the Food and Drug Administration ("FDA") to Morton Grove concerning Lindane promotional material prepared and disseminated by former Lindane marketer, Alliant Pharmaceuticals. In its response brief, the NPA concedes defeat on the first issue, withdrawing 17 of its 22 prior defenses. The NPA devotes its entire response to arguing that its remaining references to the warning letter and boxed warning are permissible.

Key to the Court's analysis, however, is the fact that the NPA does not argue that either of these issues form the predicate for any of the NPA's claims. Rather, the NPA argues that the material provides "context" for the statements at issue. (Br. at 1, 4.) Instead, its inclusion in the case will result in significant prejudice to Morton Grove, delay for the Court, and confusion for the jury. This is particularly true when Morton Grove contests many of the

allegations in the FDA's warning letter—leading to a "trial within a trial" on an initial government agency position, which is inadmissible as a matter of law.

Rule 12(f) of the Federal Rules of Civil Procedure provides that a motion to strike is appropriate where a pleading raises matters that are "immaterial, impertinent and scandalous." And, granting such a motion is particularly appropriate here where a party raises issues for little purpose other than broad, expensive and harassing discovery. Not only is it expensive for the parties, but inevitably leads to further discovery disputes and the wasting of scarce judicial resources on matters that can never be presented at trial. Morton Grove's motion to strike should be granted.[1]

ARGUMENT

I. NPA'S ALLEGATIONS ABOUT FDA'S WARNING LETTER AND BOXED WARNING ARE IMMATERIAL, IMPERTINENT, AND SCANDALOUS

NPA's allegations concerning the FDA's warning letter and boxed warning are a vehicle for NPA to obtain broad, abusive and expensive discovery on matters that are not even related to the alleged false statements. These allegations do not in any way bear on the issue of the truth or falsity of either Morton Grove's or NPA's statements. As explained in detail below, the FDA warning letter and boxed warning are not even the alleged promotional material that is the subject of the NPA's claims.

[1] Fueled by a $5 million insurance policy, the NPA seeks an ever expanding list of deponents (19 by current count)—with more witnesses demanded nearly every week. More than half relate to these issues and the NPA's counterclaim. In contrast, and given what are the real issues in dispute, Morton Grove has noticed just three depositions to date. Morton Grove is a small generic drug company. It did not invent lindane medications and has not employed scientific witnesses involved in the development of the product as one would if the case involved a proprietary product. It did not do much in-house marketing of lindane medications. It historically had no Lindane brand manager. It has simply formulated Lindane medications and sold them through a generic drug distribution chain just like it did for over 100 other drugs.

A. The FDA Allegations Have No Relation To The Statements At Issue In NPA's Counterclaim

The FDA warning letter addressed three promotional pieces: the Alliant websites www.lindane4lice.com and www.alliantpharma.com/alliant_products.html, and *The Nit Picking News* newsletter. These promotional materials, developed and utilized by a former marketing agent Alliant Pharmaceuticals, which were the subject of the FDA warning letter, are ***not*** the subject of the NPA's counterclaim. (*Compare* Ex. A, Promotional materials on Alliant websites and *The Nit Picking News*,[2] *with* Countercl. Exs. B-I.) These materials are not related in any way. Indeed, not a single one of the allegedly misleading statements in the NPA's counterclaim was derived from or relates in any way to these Alliant promotional materials. Rather, the NPA's "creative" counterclaim challenges the "Lindane Information Fact Checker" portion of www.lindane.com, five lobbying letters written to key opinion leaders involved in the Michigan political debate regarding pending legislation, and two letters written to a Michigan assemblywoman.

The NPA's attempts to inject the warning letter allegations concerning Alliant promotional materials into the matter because they claim it provides the "context" for the allegedly misleading statements are highly inappropriate. There is absolutely no correlation between www.lindane.com and www.lindane4lice.com—beyond use of the word "lindane." There is no allegation that the websites were jointly developed (they were not), jointly

[2] Morton Grove has received just this one FDA warning letter regarding the promotion of lindane in the last 15 years. Morton Grove has been extremely responsive and respectful of the FDA's point of view regarding the 3 Alliant prepared and disseminated communications in question but maintains that there was no intent to mislead, that it disagrees with many of the FDA DDMAC Division's statements contained in the Warning Letter as incorrect and actually contrary to the conclusion of others Divisions within FDA. Further, that the FDA's concerns occurred at a time when the marketing of lindane was not handled by Morton Grove, but rather subcontracted to a marketing vendor–Alliant Pharmaceuticals. Finally, Alliant had been terminated by MPG and the materials were pulled from use long before Morton Grove was contacted by the FDA, and the company has since taken corrective actions to the satisfaction of the FDA.

administered (they were not), or that the FDA has any concern or issue with respect to Morton Grove's website www.lindane.com that NPA claims contains false advertising. None of the matters cited by the FDA in its warning letter concerning the Alliant website www.lindane4lice.com and www.alliantpharma.com/alliant_products.html are alleged by the NPA to be the "false advertising" in this case. Ironically, and perhaps reflecting its true motives, the NPA instead attacks Morton Grove's legislative policy website: www.lindane.com.

Tellingly, the NPA has ***admitted already*** that what is at issue is just a *portion* of www.lindane.com, and ***not*** the Alliant websites: www.lindane4lice.com and www.alliantpharma.com/alliant_products.html, which are given no mention or reference in the Counterclaim. (Ex. B, NPA's Response to Morton Grove's Second Set of Requests to Admit No. 5 ("In particular, NPA objects to this Request because what is at issue in NPA's Counterclaim is whether the specific Morton Grove statements identified in the Counterclaim, not the whole websites, constitute false or misleading advertising that has injured or is likely to injure NPA . . ."). The NPA cannot have it both ways.

Further, the FDA warning letter and boxed warning are not admissible at trial. The FDA considers warning letters to be "informal and advisory" which do "not commit FDA to taking enforcement action." Food and Drug Administration, Regulatory Procedures Manual, Chapter 4, Advisory Actions , § 4-1-1 (Mar. 2008) (attached as Ex. C).[3] As such, FDA "does not consider Warning Letters to be final agency action[.]" *Id.*; *accord Genendo Pharm. N.V. v. Thompson*, 308 F. Supp. 2d 881, 885 (N.D. Ill. 2003) (stating that statements from agency officials below the level of Commissioner "do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence"); *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 945-46

[3] Available at http://www.fda.gov/ora/compliance_ref/rpm/pdf/ch4.pdf

(E.D. Wis. 2008) (determining FDA letters not final action); *Dietary Supplemental Coalition, Inc. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992) ("regulatory letters do not constitute final agency action."), *cert. denied*, 508 U.S. 906 (1993).

As an initial agency determination, the FDA warning letter finds no refuge under Federal Rule of Evidence 803(8)(C). In *Toole v. McClintock*, 999 F.2d 1430, 1433-35 (11th Cir. 1993), the Eleventh Circuit reversed the district court's decision admitting the FDA's "proposed findings on risk" created by certain medical devices. The court explained that the FDA report contained no findings specifically about the products at issue, but rather proposed findings about the products generally. *Id.* at 1434. The FDA report also lacked trustworthiness because it contained only "proposed" findings. *Id.* at 1434-35 (explaining that FDA's proposed findings were inferred from articles in medical journals and therefore the "tentative and second-hand nature of the findings in the report should have kept it out of evidence"). In excluding the FDA report, the court observed that Rule 803(8)(C) "makes no exception for tentative or interim reports, subject to revision and review." *Id.* The FDA warning letter deserves no exception. *See also* Part B *infra* citing cases discussing exclusion of initial agency findings under Rule 403.

Likewise, NPA's assertion that Morton Grove "concedes the relevance of the FDA's actions by referring to the FDA numerous times in its complaint" is baseless. NPA misconstrues the meaning of Paragraph 9 of Morton Grove's complaint, which referred to a change in the size of Lindane prescription bottles from 16 ounces to 2 ounces and that Lindane is an FDA approved product. (Dkt. No. 1, e.g. Compl. ¶¶ 1, 9.) Obviously, these are final agency determinations (unlike a warning letter) and the case law universally recognizes that basic product attributes and qualities (e.g. FDA approved to market the product at issue) are admissible—all in sharp contrast to reference to a contested initial agency determination about

promotional materials that are not even the challenged advertising at issue and were prepared by and disseminated by another marketing group and not used for more than a year.

Finally, plaintiffs may not seek to enforce the Food, Drug and Cosmetic Act ("FDCA") through the Lanham Act. *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 947 (E.D. Wis. 2008) (dismissing Lanham Act claim because "[b]y requesting the court to determine whether the defendants can continue to market their prescription-only . . . products, [plaintiff] is in effect asking the court to step into the shoes of the FDA" and the FDA had yet to make a final determination regarding the marketing and labeling issues). The cases relied upon by NPA do not indicate otherwise. *Genderm Corp. v. Biozone Labs.*, No. 92 C 2533, 1992 WL 220638 (N.D. Ill. Sept. 3, 1992) and *Ehrhart v. Synthes*, No. 07-01237, 2007 WL 4591276 (D.N.J. Dec. 28, 2007) merely explain that false statements are actionable under the Lanham Act even where products regulated by the FDA are involved. Morton Grove does not disagree. What Morton Grove does take issue with is the NPA's own admission contained in its response brief that its counterclaim is premised on Morton Grove's efforts to "downplay the risks of its own products in order to encourage doctors to prescribe and consumers to use its lindane products." (Br. at pg. 4.) Even if these outlandish allegations were true, they ring of an FDCA violation, not a Lanham Act violation.

B. The FDA Allegations Are Scandalous and Unduly Prejudicial

The NPA's allegations concerning the FDA warning letter and the boxed warning should be stricken under Rule 12(f) as "scandalous and unduly prejudicial." Taken in isolation, these allegations insinuate that the FDA believes Morton Grove's Lindane medications to be unsafe, which is exactly opposite of their position—Lindane medications are viewed by the FDA as safe and effective when used as directed. The FDA has maintained this position for all 57

years that Lindane medications have been on the market, despite over a dozens safety reviews of the products.

At base, the NPA would chastise Morton Grove for promoting lindane despite having a boxed warning. However, there are more than 400 products on the market with boxed warnings, many of which are actively promoted, including birth control pills, hypertensive medications and antibiotics. A boxed warning does not mean that a product is not safe to use, but rather is intended to enhance a product's safety. Given this counterclaim, allegations of impropriety relating to the marketing of a product with a boxed warning are therefore immaterial and impertinent.

The NPA, of course, cavalierly responds to this argument by noting "Morton Grove will be free to argue its position concerning the meaning and importance of these actions taken by the FDA . . . " (Br. at pg. 6.) This argument demonstrates exactly why the NPA's allegations must be rejected—(1) this Court cannot supplant its judgment for the FDA's and (2) the FDA cannot appear at trial to explain what its judgment actually is. The only thing that can come of these allegations—which have no relation to the actual claims at issue—is the parties will spend thousands of dollars retaining FDA experts to testify at trial, which will only serve to unnecessarily extend the trial and confuse the jury with matters that have previously been determined to be inadmissible as a matter of law.

With respect to the warning letter, and as discussed above, it is not a final agency decision and should be stricken for the reasons noted above, but courts in this district have also excluded agency reports as unduly prejudicial in those instances when "presenting the administrative findings . . . is tantamount to saying this has already been decided and here is the decision." *Brom v. Bozell, Jacobs, Kenyon & Eckhardt, Inc.*, 867 F. Supp. 686, 692 (N.D. Ill.

1994). Federal Rule of Evidence 403 should similarly be applied in this case to prevent the admission of the FDA warning letter. Introduction of the warning letter may inaccurately suggest to the jury that the FDA found that Morton Grove acted improperly when, in fact, letters are not the final and official position of the FDA. Thus, jurors might attach undue significance to the contents of the letter simply because it came from a government agency—even though it involves a website and promotional materials that are not even in issue. *See City of New York v. Pullman Inc.*, 662 F.2d 910, 915 (2d Cir. 1981) (holding that a preliminary finding of an agency was not admissible as it could mislead jurors because it may carry "'an aura of special reliability and trustworthiness' . . . not . . . commensurate with actual reliability."); *Tullos v. Near North Montessori School, Inc.*, 776 F.2d 150, 154 (7th Cir. 1985) ("the district judge may factor into his decision 'the danger of unfair prejudice to the defendant' and that the 'time spent by the defendant in exposing the weakness of the [FDA findings] would add unduly to the length of the trial.") (citation omitted).

The jury's inquiry should be simple—are the statements at issue false and deceptive? The NPA's statements about the warning letter and boxed warning (as argued by the NPA) are not probative to that inquiry and must be balanced with their prejudicial effect. *See G-I Holdings, Inc. v. Baron & Budd*, 238 F. Supp. 2d 521, 555-56 (D.C.N.Y. 2002) (striking allegations which "harm [defendant] in the public eye and could influence prospective jury members" and which had "no bearing on" the case). Particularly here, the allegations should be stricken because the FDA's warning letter has absolutely nothing whatsoever to do with the statements that are at issue in the NPA's counterclaim, the FDA's position was an initial agency determination (objected to by Morton Grove), and the warning letter involved the Alliant website and marketing material. Allowing the NPA's scandalous allegations to remain in its

Counterclaim will inevitably result in costly, contentious and significant discovery and expert issues—each of which the Court will necessarily need to referee. Given the materials' prejudicial and inadmissible nature, Morton Grove respectfully requests that this Court strike these allegations.

Dated: August 7, 2008

Respectfully Submitted,

MORTON GROVE PHARMACEUTICALS, INC.

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CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of August 2008, I caused a copy of **Morton Grove Pharmaceuticals, Inc.'s Reply in Support of Its Motion to Strike Allegations and Affirmative Defenses in the National Pediculosis Association, Inc.'s Answer and Counterclaim** to be served on counsel of record via ECF electronic filing:

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